



October 9, 2000

4136 '00 NOV 16 P3:05

OCALA

2400 S.W. College Rd. #104
Ocala, FL 34474
(352) 873-0034

EAST OCALA

4901 E. Silver Springs Blvd. #106
Ocala, FL 34470
(352) 236-5114

GAINESVILLE

4210 N.W. 37th Pl. #500
Gainesville, FL 32606
(352) 377-4111

CHIEFLAND

#17 N.E. 3rd St.
Chiefland, FL 32626
(352) 493-7830

LEESBURG

32703 Radio Rd. #B
Leesburg, FL 34788
(352) 326-4079

LADY LAKE

Lady Lake, FL 32159
(352) 750-2005

Honorable Donna Shalala
Secretary of Health and
Human Services
200 Independence Avenue, S.W.
Room 615F
Washington, D.C. 20201

Dear Secretary Shalala:

As a small business owner and hearing health care provider, I write with respect to hearing aids. As the AARP has confirmed, hearing aids are highly effective but dramatically underutilized medical devices.

I am very concerned with reports that the Food and Drug Administration (FDA) has reportedly sent to you a proposal for revising the current regulations governing the dispensing of hearing aids in this country that would dramatically increase the cost of hearing health care services and restrict access to hearing health care providers. Please stop and carefully consider the impact that this proposed rule will have on the small business hearing aid specialists. In particular, please ensure that any proposed rule meets the obligations of the Small Business Regulatory Enforcement Fairness Act.

Hearing impairment is a major health care concern. Please don't let the FDA put forth their proposed rule that would impede access to needed hearing health care services for millions of Americans.

Very truly yours,

Billy R. Knight
BC - HIS

BRK:jay

93N 0372

C4955